I024733

Bayer CropScience



Bayer CropScience

P O Box 12014 RTP, NC 27709 Tel 919 549-2000

November 30, 2012

Document Processing Desk 6(a)(2) Office of Pesticide Programs (7504P) U. S. Environmental Protection Agency Room S-4900, One Potomac Yard 2777 South Crystal Drive Arlington, VA 22202-4501

RE: 6(a)(2) Incidents Accumulated for the Month of October 2012

Dear Sir/Madam:

Reportable incidents accumulated for the month of October 2012 for Bayer CropScience and Bayer Environmental Science are attached.

The information with this letter is being submitted to the EPA pursuant to the Agency's interpretation of requirements imposed on registrants by Section 6(a)(2) of FIFRA. This information does not necessarily constitute additional factual information regarding unreasonable adverse effects within the meaning of 6(a)(2). It is being submitted to enable the Agency to make its own assessment of the information.

We appreciate the extra time to properly process these reports granted by EPA. If you have questions or concerns, please do not hesitate to contact me at any time.

Sincerely,

Gerret Van Duyn Compliance Manager

5. Sevet Van Duyn

State Regulatory and Documentation Services

919-549-2914

CC: AE Coordinator, CA Department of Pesticide Regulation
Jeanine Broughel, NY Department of Environmental Conservation

/attachment

Bayer CropScience, Regulatory Affairs

-003

Row 1 Administrative Data	required information. If required data field in Reporter Name		Submission date. 11/30/2012	Contact perso			Internal ID 1053107	
	Address			Address				
				Phone #				
	Incident Status: New Location and Florence, K1 USA Unknown		date of incident	Date registrant became aware of incident. 10/06/2012		Was incident part of larger study?		
ow 2 EPA Registration # (Product 1) 72155-80 esticide(s) evolved		oduct 1)	EPA Registration # (Product 2) Unknown		torre (Mills	EPA Registration # (Product 3) Unknown		
	A.I. (s) Beta-Cyfluthrin, sodium ophenylphenate Product 1 name Home Pest plus Germ Killer Indoor & Outdoor Killer RTU (1 Gal) Exposed to concentrate prior to dilution? No		A.I. (s) Unknown Product 2 Name Foggers Nonspecific Exposed to concentrate prior to dilution? No		44	A.I. (s) Unknown		
00000					Product 3 Name Bed Bug Powder Nonspecific			
0 0 0						Exposed to concentrate prior to dilution? <i>No</i>		
•	Formulation RTU		Formulation		Formulation			
Row 3 ncident Circumstances	Evidence label directions were not followed? Yes Intentional misuse? Yes Applicator certified? UNK	yard, school nursery/gree commercial woods, agric way (rail, ut	Incident site: (examples incluyard, school, industrial, nursery/greenhouse, surface v commercial turf, building/offi woods, agricultural (specify c way (rail, utility, highway)). Own Residence		Situation (act of using product): (examinclude mixing/loading, reentry, applie transportation, repair/ maintenance of application equipment, manufacturing formulating). See Incident Description Notes		ntry, application tenance of ufacturing/	
e 60 0 0 0	How exposed: (examples include direct contact with treated surface, ingestion, spill, drift, runoff) See Incident Description Notes							

Voluntary Industry Reporting Form for 6(a)(2) Adverse Effects Incident Information

Provide all known, required information. If required data field information is unknown, designate as such in appropriate area Page 2 of 3

Brief description of incident circumstances.

Miller, Lucy Oct 6 2012 12:20PM

Caller presents a complicated history of events following a series of illnesses that she had over the past 4-5 months and is concerned that it may be linked to her husband's gross misuse of this product over that period of time, indicating (by her estimates) her husband has used fifteen (15) 1-gallon containers of this product in their home due to a suspected bed-bug infestation spraying 2 rooms / day over that time period. She also notes that he has used other (unspecified) pesticide products including those in a powder form, foggers as well as glue traps / glue pads. Although she cannot identify a specific exposure per se she indicates she seems to be able to detect some sort of odor / smell in the air and is concerned that she is somehow inhaling something that is making her ill.

In brief, since June, she has been seen at her local hospital's ER 8 times for a constellation of symptoms which have included weight loss (30# over 4-5 months), dehydration, repeated episodes of vomiting, bloody noses, alteration or loss of sense of taste, ear aches and in the past 3 weeks she has developed intermittent numbness on one side of her body involving her hand and arm (unable to describe which side) and an apparent inability to bend/move one of her legs.

She has been seen by multiple physicians over the course of this time. Routine and focused diagnostic work-ups over this period of time have identified: low WBC, anemia, low potassium, kidney stones, blood in the urine and "thickening" in two chambers of her heart by a sonogram. Despite the diagnostic work-ups no formal diagnosis has been provided, none of the pesticide products used have been implicated and one of her healthcare providers has suggested an evaluation at the Cleveland Clinic but has declined to follow up on that yet.

A: The sxs described do not fit the toxicological profile of this product when used according to labeled use. Recommend the caller continue to work w/her MD's to r/o other etiologies. If any of her MD's have questions regarding this product please have them call 24/7 for any further information. Gave cs # cb prn

Sent to lead tox.

LeMaster, Steve Oct 9 2012 10:19AM Reviewed

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Voluntary Industry Reporting Form for 6(a)(2) Adverse Effects Incident Information Provide all known, required information. If required data field information is unknown, designate as such in appropriate area Page 3 of 3

Demographic information: Age: 52 Year(s) Sex: Female Occupation (if relevant) NA	Exposure route: Unknown route	Was adverse effect result of suicide/homicide or attempted suicide/homicide?	Was protective clothing worn (specify)? None Reported
If female, pregnant?	Was exposure occupational? Not indicated If yes, days lost due to illness: NA	Time between exposure and onset of symptoms: Sporadic onset of multiple symptoms	The state of the s
Type of medical care sought: (examples include none, clinic, hospital emergency department, private physician, PCC, hospital inpatient). ER/Hospital-treated & released	List signs/symptoms/adverse efficardiovascular-Cardiac hypert Neurological-Numbness Dermatological-Skin peeling Gastrointestinal-Loss of Taste (Gastrointestinal-Emesis/Vomite Heme/Hepatic-Hypokalemia	If lab tests were performed, list test names and results (If available, submit reports) None Reported	
Exposure data: NA Amount of pesticide: NA Exposure duration: Acute < 8hrs Patient weight: Unknown	Genitourinary-Hematuria Genitourinary-Kidney Stones Miscellaneous-Dehydration Miscellaneous-Weight loss Respiratory-Nose Bleed Heme/Hepatic-Anemia		
Human severity category:	Miscellaneous-Ear Pain Heme/Hepatic-Leukopenia (lov	v WBC)	the white-property

This box can be used to provide any explanatory or qualifying information surrounding the incident. (add additional pages if necessary)

Internal ID # 1053107

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Voluntary Industry Reporting Form for 6(a)(2) Adverse Effects Incident Information Provide all known, required information. If required data field information is unknown, designate as such in appropriate area Page 1 of 3 Row 1 Internal ID Reporter Name Submission Contact person (if different than reporter) date. 1054705 Administrative 11/30/2012 Data Address Address Phone # Incident Status: Location and date of incident Was incident part of larger study? Date registrant New Maryville, TN became aware of USA incident. 09/25/2012 10/09/2012 Row 2 EPA Registration # (Product 1) EPA Registration # (Product 2) EPA Registration # (Product 3) 72155-80 Pesticide(s) Involved A.I. (s) A.I. (s) A.I. (s) Beta-Cyfluthrin, sodium ophenylphenate Product 3 Name Product 1 name Product 2 Name Home Pest plus Germ Killer Indoor & Outdoor Killer RTU (1 Gal) Exposed to concentrate prior to Exposed to concentrate prior to Exposed to concentrate prior to dilution? No dilution? dilution? Formulation RTU Formulation Formulation Row 3 Evidence label Incident site: (examples include home, Situation (act of using product): (examples directions were not yard, school, industrial, include mixing/loading, reentry, application, Incident followed? No nursery/greenhouse, surface water, transportation, repair/ maintenance of Circumstances Intentional misuse? commercial turf, building/office, forest/ application equipment, manufacturing/ woods, agricultural (specify crop) right-offormulating). See Incident Description Notes way (rail, utility, highway)). Applicator certified? Own Residence **UNK** How exposed: (examples include direct contact with treated surface, ingestion, spill, drift, runoff) See Incident **Description Notes**

Voluntary Industry Reporting Form for 6(a)(2) Adverse Effects Incident Information

Provide all known, required information. If required data field information is unknown, designate as such in appropriate area

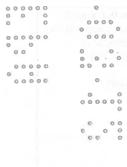
Page 2 of 3

Brief description of incident circumstances.

Keyler, Courtney Oct 9 2012 4:13PM warm transfer

Hx: Caller states her husband used product in their house 2 weeks ago. Caller states 3-4 days later he began to cough and wheeze. Caller's husband went to MD yesterday, xray was performed and they found fluid in the lungs. MD did not think sxs were related to product. MD prescribed husband levofloxacin, furosemide. Caller states her husband has a f/u with MD in 1 week.

A: We would not anticipate any s/sxs to develop from the exposure. Product has a wide margin of safety. When product is being sprayed and it's airborne, some people may develop non-specific sxs i.e respiratory irritation, coughing, headache. By removing oneself from the treated area, sxs typically resolve within 20 minutes. We would not expect delayed effects nor should it cause fluid in the lungs. Other causes may need to be considered. Have MD call if they have any questions. If you have any other questions or concerns please callback 24/7. Gave case #



Voluntary Industry Reporting Form for 6(a)(2) Adverse Effects Incident Information

Provide all known, required information. If required data field information is unknown, designate as such in appropriate area Page 3 of 3

Demographic information: Age: 84 Year(s) Sex: Male Occupation (if relevant) NA	Exposure route: Unknown route	Was adverse effect result of suicide/homicide or attempted suicide/homicide?	Was protectiv worn (specify None Reporte)?
If female, pregnant? NA	Was exposure occupational? Not indicated If yes, days lost due to illness: NA	Time between exposure and onset of symptoms: 1 week or less	A L	
Type of medical care sought: (examples include none, clinic, hospital emergency department, private physician, PCC, hospital inpatient). Private MD/DVM-treated & released	List signs/symptoms/adverse eff Respiratory-Cough/choke Respiratory-Wheezing	ects	If lab tests we list test names available, sub None Reporte	and results (If mit reports)
Exposure data: NA Amount of pesticide: NA Exposure duration: Acute < 8hrs Patient weight: Unknown				
Human severity category: HC				0 0
This box can be used to provide necessary)	any explanatory or qualifying info	rmation surrounding the incident. (add additional pa	ages if
				0 0 0
				}

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Row 1 Administrative Data	Reporter Name		Submission date. 11/30/2012	Contact perso	n (if dif	ferent than reporter)	Internal ID 1061350
	Address		- Ven I	Address		The state of the s	ical and
				Phone #	30 =		
	Incident Status: New Location and Rochester, N USA Unknown		date of incident	Date registrant became aware of incident. 10/22/2012		Was incident part of larger study?	
Row 2 Pesticide(s) Involved	EPA Registration # (Pro 72155-80	oduct 1)	EPA Registration	on # (Product 2)		EPA Registration #	(Product 3)
	A.I. (s) Beta-Cyfluthrin, sodius phenylphenate	m o-	A.I. (s)			A.I. (s)	
0 0	Product 1 name Home Pest plus Germ & Outdoor Killer RTU		Product 2 Name			Product 3 Name	
0 0 0	Exposed to concentrate dilution? <i>No</i>	prior to	Exposed to cond dilution?	centrate prior to	- X-111-X	Exposed to concentration?	ate prior to
	Formulation RTU		Formulation			Formulation	
Row 3 Incident Circumstances	Evidence label directions were not followed? No Intentional misuse? No Applicator certified? UNK	yard, school nursery/gree commercial woods, agric	e (examples inclu , industrial, enhouse, surface v turf, building/offi cultural (specify c ility, highway)).	vater, ce, forest/	includ transp applic formu	ion (act of using produle mixing/loading, ree portation, repair/ maintation equipment, manulating). **Recognition of the content of the cont	ntry, application tenance of sufacturing/
	How exposed: (examples include direct contact with treated surface, ingestion, spill, drift, runoff) See Incident Description Notes						,

Voluntary Industry Reporting Form for 6(a)(2) Adverse Effects Incident Information

Provide all known, required information. If required data field information is unknown, designate as such in appropriate area

Page 2 of 3

Brief description of incident circumstances.

Nordaune, Abby Oct 22 2012 9:33AM

Hx: Caller is an MD who states that his patient arrived 1day prior to the call with an intraventricular hemorrhage. She was intubated upon arrival. A bottle of the product (size unk) was found in the room with her and a family member states she had been spraying prior to being found. It is unk when she used the product or if and how she could have come into contact with it. Caller would like to know if anything like her sxs have been reported in the past and what would be expected from an exposure. He states she is heading toward end-of-life care at the time of the call. He does not have the product with him at the time of the call.

A: Advised caller of the wide-margin of safety of permethrin-based products. If she got it on her skin, it would not be expected to absorb systemically from a casual exposure, although it may cause transient skin irritation, and may cause transient GI upset if ingested. If breathed in it could cause transient respiratory irritation. However, with normal use as directed, we would not expect to see adverse health effects. This information will be documented and reported for the company. Provided caller with case # and advised to cb 24/7 prn with further questions or concerns.

LeMaster, Steve Oct 22 2012 3:27PM Call to MD at:

Reports that this is a 52 y/o F who lives with her sister and has a h/o HTN, asthma and a vague history of a single seizure at some time in the past and according to records takes Lisinopril Amlodipine and Certraline. She was in her usual state of health yesterday when she began to feel progressively ill over the course of several hours initially c/o nausea, some vomiting and suddenly becoming unresponsive and having seizure activity (unknown if status vs. multiple repeated seizures). EMS was immediately notified and was transported to hospital. She is currently unresponsive on a ventilator and other life support.

CT scan of the brain shows an intra-ventricular hemorrhage. Further consult and imaging studies by neuro-surgery group is investigating if there were underlying brain structural issues that pre-dated this event that can be identified however there is apparently no family history of such events.

She remains on life support Her prognosis has been listed as 'poor' and family is in consult with hospital staff regarding 'end of life care' in general

Her use / exposure to the product is unclear (if any). It is known that she had been spraying this product around the house recently due to some sort of pest infestation though other details of product use or any exposure to it are not known.

They have a copy of the MSDS for product and Neuro-surgery group asked him to attempt to determine if any use/exposure may be associated with the effects that she had. There is no allegation that product is involved just that it was found at the scene / in the home and wanted to ensure they had been through in their investigation.

EPA REG#: 72155-80 (per caller)

A: Agreed with previous specialists assessment and there is no indication that product would be involved with the effects noted. If additional questions arise, please do call back - provided caller my name and direct # at SCI as well as the case# to reference.

Call to Bob Montano at Bayer - LM on VM as the the case at this time. Will forward report as well.

Voluntary Industry Reporting Form for 6(a)(2) Adverse Effects Incident Information

Provide all known, required information. If required data field information is unknown, designate as such in appropriate area Page 3 of 3

Demographic information: Age: 52 Year(s) Sex: Female Occupation (if relevant) NA	Exposure route: Unknown route	Was adverse effect result of suicide/homicide or attempted suicide/homicide?	Was protective clothing worn (specify)? None Reported
If female, pregnant? NO	Was exposure occupational? Not indicated If yes, days lost due to illness: NA	Time between exposure and onset of symptoms: Unable to determine	And the second s
Type of medical care sought: (examples include none, clinic, hospital emergency department, private physician, PCC, hospital inpatient). <i>ER/Hospital-admitted</i>	List signs/symptoms/adverse eff Gastrointestinal-Nausea Gastrointestinal-Emesis/Vomiti Neurological-Intracranial Blee Neurological-Seizure (Pattern	If lab tests were performed, list test names and results (If available, submit reports) None Reported	
Exposure data: NA Amount of pesticide: NA Exposure duration: Acute < 8hrs Patient weight: Unknown			10. 15 test and passed from
Human severity category: HB			A CONTRACTOR OF THE STATE OF TH

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Internal ID# 1061350

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Voluntary Industry Reporting Form for 6(a)(2) Adverse Effects Incident Information Provide all known, required information. If required data field information is unknown, designate as such in appropriate area Page 1 of 3 Row 1 Reporter Name Submission Contact person (if different than reporter) Internal ID date. 1062114 Administrative 11/30/2012 Data Address Address Phone # Incident Status: Location and date of incident Date registrant Was incident part of larger study? New Colleen, TX became aware of **USA** incident. 10/23/2012 10/23/2012 Row 2 EPA Registration # (Product 1) EPA Registration # (Product 2) EPA Registration # (Product 3) 72155-80 Pesticide(s) Involved A.I. (s) A.I. (s) A.I. (s) Beta-Cyfluthrin, sodium ophenylphenate Product 1 name Product 2 Name Product 3 Name Home Pest plus Germ Killer Indoor & Outdoor Killer RTU (1 Gal) Exposed to concentrate prior to Exposed to concentrate prior to Exposed to concentrate prior to dilution? No dilution? dilution? **Formulation** Formulation Formulation Incident site: (examples include home, Row 3 Evidence label Situation (act of using product): (examples directions were not yard, school, industrial, include mixing/loading, reentry, application, Incident followed? No nursery/greenhouse, surface water, transportation, repair/ maintenance of Circumstances Intentional misuse? commercial turf, building/office, forest/ application equipment, manufacturing/ woods, agricultural (specify crop) right-of-No formulating). way (rail, utility, highway)). See Incident Description Notes Applicator certified? Own Residence UNK How exposed: (examples include direct contact with treated surface, ingestion, spill, drift, runoff) See Incident **Description Notes**

Voluntary Industry Reporting Form for 6(a)(2) Adverse Effects Incident Information

Provide all known, required information. If required data field information is unknown, designate as such in appropriate area

Page 2 of 3

Brief description of incident circumstances.

Ferguson, Anna Oct 23 2012 12:18PM

Hx: Caller states that her 2 yo son was caught holding the product container about 15 min ago. Product was all about the floor and child's breath and body smelled of it. Child has since been given a bath. Child has welts forming on his back and swelling about his eyes. Eyes are red, and child says that they hurt.

Ferguson, Anna Oct 23 2012 12:21PM Addendum to notes: CRC transfer

Yeager, Greg Oct 24 2012 12:50PM

CB complete. Caller gave him another bath, and sxs began to improve. Sxs resolved completely later that evening.

If any new or unexpected symptoms develop, please contact us 24/7 and refer to your reference number so that we can advise on further treatment or determine if referral to a healthcare professional might be needed.

Voluntary Industry Reporting Form for 6(a)(2) Adverse Effects Incident Information Provide all known, required information. If required data field information is unknown, designate as such in appropriate area Page 3 of 3

Age: 2 Year(s) Sex: Male Occupation (if relevant) NA	Exposure route: Unknown route	Was adverse effect result of suicide/homicide or attempted suicide/homicide?	Was protective clothing worn (specify)? None Reported
If female, pregnant? NA	Was exposure occupational? Not indicated If yes, days lost due to illness: NA	Time between exposure and onset of symptoms: 30 min or less	110
Type of medical care sought: (examples include none, clinic, hospital emergency department, private physician, PCC, hospital inpatient). None	List signs/symptoms/adverse eff Dermatological-Edema/Swellin Dermatological-Hives/Welts Ocular-Ocular irritation/pain Ocular-Redness/Conjunctivitis		If lab tests were performed, list test names and results (I available, submit reports) None Reported
Exposure data: NA Amount of pesticide: NA Exposure duration: Acute < 8hrs Patient weight: Unknown			Agrania - Agrani
Human severity category:			1 (1) (1 - 1) (1) (1) (1) (1) (1) (1) (1) (1) (1)

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Voluntary Industry Reporting Form for 6(a)(2) Adverse Effects Incident Information Provide all known, required information. If required data field information is unknown, designate as such in appropriate area Page 1 of 3 Row 1 Reporter Name Submission Contact person (if different than reporter) Internal ID 1065191-1 date. Administrative 11/30/2012 Data Address Address Phone # Incident Status: Location and date of incident Date registrant Was incident part of larger study? Daytona Beach, FL became aware of New No USA incident. Chronic: >1 month <= 3 10/29/2012 months Row 2 EPA Registration # (Product 1) EPA Registration # (Product 2) EPA Registration # (Product 3) 72155-80 Pesticide(s) Involved A.I. (s) A.I. (s) A.I. (s) Beta-Cyfluthrin, sodium ophenylphenate Product 3 Name Product 2 Name Product 1 name Home Pest plus Germ Killer Indoor Insect foggers & Outdoor Killer RTU (1 Gal) Exposed to concentrate prior to Exposed to concentrate prior to Exposed to concentrate prior to dilution? No dilution? No dilution? Formulation Formulation Formulation Row 3 Evidence label Incident site: (examples include home, Situation (act of using product): (examples directions were not yard, school, industrial, include mixing/loading, reentry, application, Incident followed? No nursery/greenhouse, surface water, transportation, repair/ maintenance of Intentional misuse? commercial turf, building/office, forest/ application equipment, manufacturing/ Circumstances woods, agricultural (specify crop) right-offormulating). No way (rail, utility, highway)). See Incident Description Notes Applicator certified? Own Residence UNK How exposed: (examples include direct contact with treated surface, ingestion, spill, drift, runoff) See Incident **Description Notes**

Voluntary Industry Reporting Form for 6(a)(2) Adverse Effects Incident Information

Provide all known, required information. If required data field information is unknown, designate as such in appropriate area

Page 2 of 3

Brief description of incident circumstances.

Ferguson, Anna Oct 29 2012 9:23AM

CRC transfer: CS representative has explained that the product should be used as a crack/crevasse spray in well-ventilated areas only.

Hx: Caller and her husband have been trying to rid their home of insects for the past 2 months, first using foggers, and then beginning use of Home Pest plus Germ Killer about 1-1.5 months ago. This product was used every 2 days or so in the kitchen. Product was also sprayed under the house 4-5 days ago. For about the past 2 months, caller has found that when she wakes up in the morning, she has respiratory irritation and phlegmy cough. Since then, she has found that sx last throughout the day. She has been seen by MD x2, diagnosed with upper respiratory infection, and treated with Z-pack and amoxicillin. Sx have not improved.

Caller's husband had cough quickly after spraying the product about the divider between their kitchen and living room. This occurred some time last week, and he continues to cough at night.

A: The Home Pest product may be irritating to the respiratory tract, but is not expected to cause lasting problems. Recommend d/c use and ventilating the area. If sx persist or worsen, continue working with MD, and have MD call with product-related questions.



Voluntary Industry Reporting Form for 6(a)(2) Adverse Effects Incident Information

Provide all known, required information. If required data field information is unknown, designate as such in appropriate area Page 3 of 3

Demographic information: Age: 61 Year(s) Sex: Female Occupation (if relevant) NA	Exposure route: Unknown route	Was adverse effect result of suicide/homicide or attempted suicide/homicide?	Was protective clothing worn (specify)? None Reported
If female, pregnant? NO	Was exposure occupational? Not indicated If yes, days lost due to illness: NA	Time between exposure and onset of symptoms: Unable to determine	
Type of medical care sought: (examples include none, clinic, hospital emergency department, private physician, PCC, hospital inpatient). Private MD/DVM-treated & released	List signs/symptoms/adverse eff Respiratory-Cough/choke Respiratory-Respiratory irritation		If lab tests were performed, list test names and results (If available, submit reports) None Reported
Exposure data: NA Amount of pesticide: NA Exposure duration: Chronic: >1 month <= 3 months Patient weight: Unknown	Sand Special and Section 1 to the control of the co		

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Internal ID# 1065191-1